

### **REMARKS**

This Amendment is in response to the Office Action mailed December 29, 2003, having a three (3) month shortened statutory period for reply.

The specification of the present application has been amended for the sake of clarification or to correct inadvertent typographical errors made therein. All specification amendments are reflected in the Amendment to the Specification section (see, pages 2-3).

Claims 1, 2 and 11-19 are pending, claim 19 is newly added, and claims 3-10 are cancelled in this application.

Claims 1, 12 and 17-18 have been amended. New claim 19 recites three compounds that fall within scope of elected Group III, which respectively, are identified in Examples 8, 19 and 20 of the specification (support is found at page 25, lines 5-36 to page 26, lines 1-29 and page 30, lines 8-34 of the specification). All claim amendments are reflected in the Listing of Claims section (see, pages 4-8).

No new matter has been added to the claims or specification by the amendment. Support for all amendments are found in the originally filed claims and specification.

Attached herewith is a Supplemental Information Disclosure Statement Under 37 C.F.R. § 1.97(b).

Applicant requests consideration and entry into the record of the following amendments and remarks.

### **Information Disclosure Statement**

For the record, applicants note that an inadvertent error was made in the October 22, 2003 Information Disclosure Statement filed in the U.S. Patent Office by citing the above-identified present pending U.S. Appln. Serial No. 10/031,844, Davies et al. (P32372), instead of identifying another pending U.S. Appln. Serial No. 10/720,788, Filed November 24, 2003.

### **Election/Restriction**

For the record, applicants note that the election with traverse of:

Group III, claims 1-2 and 11-18, drawn to a compound, wherein one of one of Z<sup>1</sup>, Z<sup>2</sup>, Z<sup>3</sup> is N, and Z<sup>4</sup> and Z<sup>5</sup> are CR<sup>1a</sup>, namely isomeric bicyclo bipyridine, composition and method of use

has been acknowledged by the Examiner in the December 29, 2003 Office Action.

In light of the foregoing, applicants reserve the right to file non-elected inventions as the subject of future applications, which may derive priority from the present application without prejudice.

**Rejection Under 35 U.S.C. §112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs**

Claim 18 is rejected under 35 U.S.C. §112, 1<sup>st</sup> para., as the specification, while enabling for treating bacterial infections due to specific organisms (as defined in the specification on page 31), does not reasonably provide enablement for any or all bacterial infections.

Applicants have overcome this rejection by amending claim 18 to recite that bacterial infections treatable by methods of the present invention are caused by *S. aureus* and *S. pneumoniae* organisms in mammals (support for this amendment is found at page 31, lines 3-4 and page 7, line 35 of the specification).

Claims 1-2 and 11-18 are rejected under 35 U.S.C. §112, 2<sup>nd</sup> para., for being indefinite and for failing to particularly point out and distinctly claim the invention.

The Examiner states that the following terms are unclear or indefinite: attachment of the functional group "(NR<sup>2</sup>)R<sup>4</sup>" at the 4-position of the piperidine ring is unclear (claim 1); recitation of the group CH(R<sup>13</sup>)CO<sub>2</sub>NH<sub>2</sub> appears to be a typographical error (claim 1); the term "derivative" is indefinite, as that term can include more than what is being positively recited therein (claims 1 and 17-18); the phrase "optionally further substituted . . ." which follows CH(R<sup>13</sup>)CO<sub>2</sub>NH<sub>2</sub> is unclear as to which atom is to be further substituted; and inapplicability of the proviso of claim 1, line 30, in light of applicants' election.

In light of the foregoing, the functional group "(NR<sup>2</sup>)R<sup>4</sup>" in claim 1 has been amended by removing the parentheses to recite "NR<sup>2</sup>R<sup>4</sup>" at the 4-position of the piperidine ring and the functional group "CH(R<sup>13</sup>)CO<sub>2</sub>NH<sub>2</sub>" has been amended to recite "CH(R<sup>13</sup>)CONH<sub>2</sub>".

For the sake of clarification, amended claim 1 now recites CH(R<sup>13</sup>)CONH<sub>2</sub> is optionally further "**N-substituted** by (C<sub>1-6</sub>)alkyl, hydroxy(C<sub>1-6</sub>)alkyl, aminocarbonyl(C<sub>1-6</sub>)alkyl or (C<sub>1-6</sub>)alkenyl; hydroxy(C<sub>1-6</sub>)alkyl; carboxy; cyano or (C<sub>1-6</sub>)alkoxycarbonyl . . ." No new matter has been added in the present case, as an ordinary artisan would understand based upon the teachings of the specification and general organic chemistry principles that the only point of chemical substitution on the functional group CH(R<sup>13</sup>)CONH<sub>2</sub> is at the amide or "N-substituted" position.

The proviso at line 30 of claim 1, "provided that when Z<sup>1</sup>, Z<sup>2</sup>, Z<sup>3</sup>, Z<sup>4</sup> and Z<sup>5</sup> are CR<sup>1a</sup>, then R<sup>1</sup> is not hydrogen" has been deleted.

Claims 1 and 17-18 have been amended to delete the term "derivative" from the phrase "a pharmaceutically acceptable derivative thereof" and recite instead "a pharmaceutically acceptable **salt, ester, and/or N-oxide** derivative thereof" (support for this amendment is found at page 7, line 35 and page 8, line 24 of the specification).

In addition, the Examiner also states that generally a number of variable definitions in claim 1 are unclear.

In the interest of advancing prosecution, applicants have amended the claim language to correct for minor informalities, such as inadvertent typographical and punctuation errors (i.e., such amendments are reflected in the marked-up claim listings).

The following amendments have been made to claim 1 for further clarification:

within the  $R^3$  variable definition, the term " $(C_{1-6})$  (see, originally filed claim 1 and specification at page 3, line 7)" has been amended to recite the term " $(C_{1-4})$  **optionally substituted**" (support for this amendment is found in the specification at page 6, line 4). The identical term in corresponding claim 12 also has been amended to recite " $(C_{1-4})$  optionally substituted";

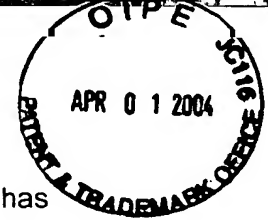
the phrase " $R^6$ ,  $R^7$ ,  $R^8$  and  $R^9$  is independently selected from . . . amino or aminocarbonyl optionally substituted as for corresponding substituents  $R^3$  (see, originally filed claim 1 and specification at page 4, line 15)" has been amended to recite " $R^6$ ,  $R^7$ ,  $R^8$  and  $R^9$  is independently selected from . . . amino or aminocarbonyl optionally substituted as for corresponding substituents  **$R^{12}$  as defined in  $R^3$** "; and

claim 1 has been amended to set forth definitions associated with the terms phenyl, benzoyl, heteroaryl and heteroaroyl groups after the listed definitions of  $R^3$  and  $R^5$  by reciting specific definitions for what substituents the aforementioned terms may be optionally substituted with (support for this amendment is found at page 7, lines 12-16 of the specification).

Applicants request further clarification by the Examiner in identifying other specific variable terms, if any, which may be unclear.

In each of the above-identified amendments, no new matter has been added to the claims of the present application.

In light of the above, applicant requests that the above rejection under 35 U.S.C. § 112, 1<sup>st</sup> and 2<sup>nd</sup> paragraphs, be withdrawn.



**Allowable Subject Matter**

Claims 1, 2 and 11-17 are indicated to be allowable if rewritten or amended to overcome the rejections of record under 35 U.S.C. § 112, 2<sup>nd</sup> paragraph. The Examiner has stated that those claims encompass specific species and composition not taught or suggested by the art of record or from a search of the relevant art area.

Applicants have overcome the rejection and amended the claims 1, 2 and 11-17 to comply with the Examiner's 35 U.S.C. §112, 2<sup>nd</sup> paragraph rejection. In light of this, applicants believe that the claims now are in condition for allowance.

**CONCLUSION**

In view of the above amendments and remarks, applicant believes that the claims of the present application are in condition for allowance and is earnestly solicited.

If any additional fees or charges are required authorization is hereby granted to charge any necessary fees to Deposit Account No. 19-2570 accordingly.

Should the Examiner have any questions or wish to discuss any aspect of this case, the Examiner is encouraged to call the undersigned attorney at the number below.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Grace Hsu", written over a horizontal line.

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